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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PAK, YONG D

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/628,693	Applicant(s) HAROCHE ET AL.	
	Examiner Yong D Pak	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8,9 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5, 8 and 26-32 is/are allowed.
- 6) ☒ Claim(s) 4 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on March 18, 2004, amending claim 3, has been entered.

Claims 1-5, 8-9 and 26-32 are pending.

Response to Arguments

Applicant's arguments, filed on March 18, 2004, with respect to claims 3-4, 8-9 and 26-29 have been fully considered and are persuasive. The rejections of claims 3-4, 8-9 and 26-29 have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The parent claim is drawn to nucleic acid molecule that hybridizes to SEQ ID NO:2. However, claim 4 adds the limitation that the nucleic acid molecule is derived by in vitro mutagenesis from a sequence selected from SEQ ID NO:2 to 15. The limitation appears to be unrelated to the scope of the nucleic acid molecule in found in claim 3.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 9 have been interpreted to claims drawn to nucleic acid molecules derived from SEQ ID NOs: 3, 4, 6, 8, 10 and 12-15 (see rejection of claims 4 and 9 under 35 USC 112, 2nd paragraph).

Claims 4 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid molecule derived by in vitro mutagenesis from SEQ ID NOs: 3, 4, 6, 8, 10 and 12-14, ranging from 15-27 nucleic acids in length which corresponds to less than 4% of the structure of SEQ ID NO:2. Therefore, these claims are drawn to a genus of vatE genes having unlimited structure. There is no evidence on the record of the relationship between the structure of a vatE gene of SEQ ID NO:2 and the structure of a vatE gene from another source. The specification fails to describe any other representative species by any identifying characteristics or properties other than the "functionality" of encoding a vatE protein and fails to provide any structure: function correlation present in all members of the claimed genus.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention

in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 4 and 9.

Claims 4 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid that hybridizes to SEQ ID NO:3 under conditions of high stringency encoding vatE proteins, does not reasonably provide enablement for a nucleic acid molecule encoding a vatE protein derived from SEQ ID NO: 3, 4, 6, 8, 10 and 12-14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification only teaches a vatE gene of SEQ ID NO:2. Despite knowledge in the art for the isolation of polynucleotides, the specification fails to provide guidance regarding how to isolate other vatE genes whose structure is different from SEQ ID NO:2 nor derived from short oligonucleotides of SEQ ID NO: 3, 4, 6, 8, 10 and 12-14.

Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other vatE proteins is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The quantity of experimentation in this area is extremely large since there is significant variability in the structure of all vatE proteins. It would require significant study to identify any vatE proteins and would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Therefore, one of ordinary skill would require guidance in order to make vatE genes having structures different from SEQ ID NO:2 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 9 are drawn to a nucleic acid molecule derived from SEQ ID NO:2 to 15 and a vector comprising said nucleic acid molecule. However, SEQ ID NOs: 5, 7, 9 and 11 are amino acid sequences.

Claims 4 and 9 are confusing. The parent claim is drawn to nucleic acid molecule that hybridizes to SEQ ID NO:2. However, claim 4 adds the limitation that the nucleic acid molecule is derived by in vitro mutagenesis from a sequence selected from SEQ ID NO:2 to 15.

Claim 4 recites the limitation "said isolated nucleic molecule" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Allowable Subject Matter

Claims 1-3, 5, 8 and 26-32 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Yong D. Pak
Patent Examiner



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